

REMARKS

Claim Amendments

Claim 23 has been amended herein to recite that the ascorbic acid is micronized in an oil and to further define the oil and non-aqueous carrier of the formulation.

Information Disclosure Statement

An Information Disclosure Statement (IDS) is being filed concurrently herewith. Entry of the IDS is respectfully requested.

Rejection of Claims 23-45 Under 35 U.S.C. §103(a)

Claims 23-45 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Siddiqui (US Patent No. 6,146,664). According to the Examiner, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to provide UV protection or treat wrinkles or to stimulate collagen production in a mammal by topically applying an ascorbic acid composition of Siddiqui.

Applicant has amended Claim 23 herein to recite that the composition to be topically applied comprises at least 30% L-ascorbic acid, by weight, micronized in oil, a non-aqueous carrier, glycerin and an exfoliant. Each of these elements is required to obtain the deep penetration of L-ascorbic acid provided by the claimed invention

Siddiqui teaches an ascorbic acid composition in a silicone vehicle. As known to one of skill in the art, silicone oil is a polymer which, when applied to the skin, acts as an additional epidermis-like lipophilic barrier that hinders the transport of water and water-soluble molecules (for example, ascorbic acid). (See e.g., Aungst, B.J., *Drug Development and Industrial Pharmacy*, v. 14 (#11): 1481-1494 (1988)) Because Siddiqui uses silicone oil, which is specifically not claimed by Applicants, very little, if any, of the ascorbic acid in the Siddiqui formulation penetrates deep into the skin. Moreover, Siddiqui is silent with regards to the use of glycerin and an enzymatic exfoliant to promote deeper penetration of the ascorbic acid. This is because Siddiqui, through the use of silicone oil, is not trying to promote deep penetration of the ascorbic acid. Rather, Siddiqui describes an occlusive ascorbic acid formulation that creates a film on the skin for the superficial treatment of the epidermis.

Siddiqui fails to teach or suggest an ascorbic acid composition of the instantly claimed formulation. As such, the claimed invention would not have been obvious to one skilled in the art at the time the invention was made. Reconsideration and withdrawal of the rejection are respectfully requested.

Rejection of Claims 23-45 Under 35 U.S.C. §103(a)

Claims 23-45 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Siddiqui (US Patent No. 6,146,664) in view of Ozlen (US Patent No. 5,441,740). According to the Examiner, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to include enzymatic exfoliants, such as the papain of Ozlen, within the ascorbic acid composition of Siddiqui.

Applicant has amended Claim 23 herein to recite that the composition to be topically applied comprises at least 30% L-ascorbic acid, by weight, micronized in oil, a non-aqueous carrier, glycerin and an exfoliant. As discussed above, Siddiqui describes an occlusive ascorbic acid formulation that creates a film on the skin that acts as an additional epidermis-like lipophilic barrier that hinders the transport of water and water-soluble molecules (for example, ascorbic acid).

The Examiner states that Olzen describes papain's exfoliating properties that when combined with the teachings of Siddiqui the expected result would be an enhanced cosmetic formulation that provides greater exfoliating benefits for better skin conditions. Applicants respectfully disagree. Olzen teaches an aqueous composition that is very different and distinct from non-aqueous compositions of Siddiqui and the instantly claimed composition. Exfoliants are only found in aqueous (water-based) formulations because the exfoliant needs to be ionized through an interaction with water to work.

Siddiqui's use of a silicone-based formulation acts as a barrier to water and to the absorption of the ascorbic acid. This problem was solved, for the first time, by Applicants use of a non-silicone based anhydrous formulation and glycerin. Glycerin, as taught at page 6, last paragraph, of the instant specification is a humectant which draws water to the surface of the skin, making the skin more permeable, while at the same time activating the exfoliant to promote deeper penetration in a way that is neither taught or suggested by the prior art. As such, the

claimed invention would not have been obvious to one skilled in the art at the time the invention was made. Reconsideration and withdrawal of the rejection are respectfully requested.

Rejection of Claims 23-45 Under 35 U.S.C. §103(a)

Claims 23-45 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Hernandez *et al.* (US Patent No. 5,843,411). According to the Examiner, Hernandez *et al.* teach an ascorbic acid formulation in a non-aqueous base or substantially anhydrous composition, thereby rendering obvious the claimed invention as a whole.

Applicant has amended Claim 23 herein to recite that the composition to be topically applied comprises at least 30% L-ascorbic acid, by weight, micronized in oil, a non-aqueous carrier, glycerin and an exfoliant.

Hernandez teaches an ascorbic acid composition in a silicone vehicle. As known to one of skill in the art, silicone oil is a polymer which, when applied to the skin, acts as an additional epidermis-like lipophilic barrier that hinders the transport of water and water-soluble molecules (for example, ascorbic acid). (See e.g., Aungst, B.J., *Drug Development and Industrial Pharmacy*, v. 14 (#11): 1481-1494 (1988)) Because Hernandez uses silicone oil, which is specifically not claimed by Applicants, very little, if any, of the ascorbic acid in the Hernandez formulation penetrates deep into the skin. Moreover, Hernandez is silent with regards to the use of glycerin and an enzymatic exfoliant to promote deeper penetration of the ascorbic acid. This is because Hernandez, through the use of silicone oil, is not trying to promote deep penetration of the ascorbic acid. Rather, Hernandez describes an occlusive ascorbic acid formulation that creates a film on the skin for the superficial treatment of the epidermis.

The examples at columns 5 and 6 of Hernandez demonstrate a 10% ascorbic acid formulation containing silicones and derivatives of silicone chemistry. As discussed above, there are significant differences between silicones and non-silicone based compositions. Thus, one skilled in the art, based on the exemplified formulations, would not have been 1) motivated to select various components from a laundry list of non-silicone derived ingredients to arrive at the instantly claimed invention; or 2) have a reasonable expectation of success that the non-silicone based compositions would effectively stabilize the ascorbic acid, much less promote deeper penetration of the ascorbic acid into the skin as taught by Applicants.

Hernandez fails to teach or suggest an ascorbic acid composition of the instantly claimed formualtion. As such, the claimed invention would not have been obvious to one skilled in the art at the time the invention was made. Reconsideration and withdrawal of the rejection are respectfully requested.

CONCLUSION

In view of the above amendments and remarks, it is believed that all claims are in

- condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner feels that a telephone conference would expedite prosecution of this case, the
- Examiner is invited to call the undersigned.

Respectfully submitted,

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